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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/551,258 | 11/24/2006 | Qiwang Xu | CCPIT-1 (IEC040017PUS) | 3347 |
| 26479 | 7590 | 09/10/2007 | EXAMINER | |
| STRAUB & POKOTYLO 620 TINTON AVENUE BLDG. B, 2ND FLOOR TINTON FALLS, NJ 07724 | | | KRISHNAN, GANAPATHY | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1623 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/551,258 | XU ET AL. | |
| | Examiner | Art Unit | |
| | Ganapathy Krishnan | 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 September 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/13/2006.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Information Disclosure Statement

Foreign language references listed in the Information Disclosure Statement, for which no English translation has been provided, have not been considered. If an English abstract has been provided for a foreign language document then only the English abstract has been considered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 and 8-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 and 8-10 provide for the use of N-acetyl-D-glucosamine, but, since the claim does not set forth any steps involved in the method, it is unclear what method applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. For the purpose of prosecution Claims 1-4 and 8-10 are interpreted as drawn to a method of treating non-specific inflammations caused by physical/chemical factors.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/550,784 ('784). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant Claims 1-4 and 8-10 are drawn to a use of N-acetyl-D-glucosamine or pharmaceutically acceptable salt thereof in treating non-specific inflammations caused by physical/chemical factors.

Claims 1-3 and 7 of '784 are drawn to a use of N-acetyl-D-glucosamine or pharmaceutically acceptable salt thereof in treating and controlling local lesions and systematic symptoms caused by infections of virus or bacteria and the use of the of N-acetyl-D-glucosamine or pharmaceutically acceptable salt thereof in the manufacture of a medicament for treating and controlling local lesions and systematic symptoms caused by infections of virus or bacteria.

Instant claims 5-7 and 11 are drawn to a method of treating non-specific inflammations caused by physical/chemical factors comprising administering a pharmaceutical composition comprising an effective amount of N-acetyl-D-glucosamine or pharmaceutically acceptable salts thereof.

Claims 4-6 of '784 are drawn to a method of treating and controlling local lesions and systematic symptoms caused by infections of virus or bacteria.

Claims 1-7 of '784 differ from the instant claims in that the instant claims are drawn to inflammations caused by physical/chemical factors. '784 defines systematic symptoms of viral and bacterial infections as fever, headache, vertigo delirium, nausea, emesis and general malaise (page 1, seconds paragraph). The terms, "general malaise" is broad and is seen to include pain. The same definition (pain) also holds good for non-specific inflammation in the instant specification (page 1, second paragraph). Since "general malaise" embraces "pain", it would have been obvious to one of ordinary skill in the art at the time the invention was made that N-

acetyl-D-glucosamine could be successfully employed in the method of '742, for the treatment of pain.

In determining the differences between the invention of '784 and the instant claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). Although the claims of '784 recite the cause of the symptoms (which includes pain) to be virus or bacterial infection, one of ordinary skill in the art would readily recognize that the method taught by '784 could be employed in the method of treating non-specific inflammations (including pain) as recited in the instant claims. One of ordinary skill in the art is seen as one having a PhD. The use of known active agent in the treatment of the same type of symptoms and conditions taught in the prior art is not seen to render the instantly claimed method patentable over '784. Once the general method and active agent have been shown to be useful for treating a particular symptom or condition, the burden is on the applicant to present reason or authority for believing that the same symptoms caused by bacteria or virus cannot be treated by using the same active agent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Burton et al (US 5,217,962).

Burton et al teach the oral administration of N-acetyl glucosamine for the treatment of irritable bowel syndrome. This condition is caused by damage of the gastrointestinal tract by corrosive digestive juices, which is acidic (non-specific inflammation cause by chemical factor; col. 3, lines 13-22; col. 4, lines 23-49). The dosage is about 300mg to 10,000g per day (col. 2, line 65 through col. 3, line 3; col. 5, Example 1) and the N-acetyl glucosamine can be taken in the form of capsules (medicament; col. 6, lines 23-25). This teaching of Burton is seen to meet the limitations of instant claims 1-11.

Conclusion

Claims 1-11 are rejected

Art Unit: 1623

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK


Patrick T. Lewis
Primary Patent Examiner
Art Unit 1623